

Exhibit C

*State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v.
Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS*

**Exhibit to the November 25, 2009 Declaration of Christopher C. Palermo
in Support of Mylan's Motion for Partial Summary Judgment**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF THE DISTRICT OF COLUMBIA

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Montgomery, AL 36130;

THIRD AMENDED COMPLAINT

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CASE NUMBER: 1:98CV03115

JUDGE: Thomas F. Hogan

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Plaintiffs,)

v.)

MYLAN LABORATORIES, INC.,)
130 Seventh Street,)
1030 Century Building,)
Pittsburgh, Pennsylvania 15222;)

CAMBREX CORPORATION,)
One Meadowlands Plaza)
East Rutherford, New Jersey 07073;)

PROFARMACO S.R.L.)
Via Cucchiari, 17)
I-20155 Milano, Italy;)

GYMA LABORATORIES)
OF AMERICA, INC.,)
135 Cantiague Rock Road,)
Westbury, New York 11590;)
SST CORPORATION,)
635 Brighton Road,)
Clifton, New Jersey 07015,)
Defendants.)

I.

SUMMARY OF COMPLAINT

1. The States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin, Wyoming; the Commonwealths of Kentucky, Massachusetts, Pennsylvania, and Virginia; and the District of Columbia (collectively, Plaintiff States or States), by and through their Attorneys General, bring this action individually and as authorized by law, as representatives of, and as *parens patriae* on behalf of, natural persons in their respective States; on behalf of their respective States' general economies in their sovereign capacities; and in their proprietary capacities on behalf of departments, bureaus and agencies of state government as injured purchasers or reimbursers, against Defendants Mylan Laboratories, Inc.

(Mylan), Cambrex Corporation (Cambrex), Profarmaco S.r.l. (Profarmaco), Gyma Laboratories of America, Inc. (Gyma), and SST Corporation (SST) (collectively, Defendants).

2. The States seek relief to remedy and compensate for injuries sustained as a result of the Defendants' violations of the antitrust laws of the United States and related laws of the States.

The States allege Defendants Mylan, Cambrex, Profarmaco and Gyma: 1) conspired to monopolize the markets for generic lorazepam tablets and generic clorazepate tablets; and 2) entered into unlawful contracts, combinations and conspiracies relating to the supply of the active pharmaceutical ingredients (APIs) for clorazepate and lorazepam in unreasonable restraint of trade. The States further allege Defendant Mylan attempted to monopolize and did in fact unlawfully monopolize the markets for generic lorazepam and generic clorazepate tablets. The States also allege Defendants Mylan, Cambrex, Profarmaco, Gyma and SST conspired and agreed to fix, raise, or stabilize the prices of lorazepam API. Finally, the States allege supplemental state law claims.

II.

JURISDICTION AND VENUE

3. This Complaint, which alleges violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, is filed under and jurisdiction is conferred upon this Court by Sections 4, 4c, 12 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 15c, 22 and 26, and 28 U.S.C. §1331.

4. This Complaint also alleges violations of state antitrust and/or unfair competition statutes and related state laws as set forth in Paragraphs 96 through 212 below, and seeks damages, civil penalties and equitable relief under those state laws for claims brought by the Plaintiff States. All claims under federal and state law are based upon a common nucleus of operative facts and the

entire action commenced by this Complaint constitutes a single case which would ordinarily be tried in one judicial proceeding.

5. This Court has jurisdiction of the action under the provisions of 28 U.S.C. §§ 1331, 1337 and 1367(a), as well as under the principles of supplemental jurisdiction. Supplemental jurisdiction would avoid unnecessary duplication and multiplicity of actions in law and in equity, and should be exercised in the interests of judicial economy, convenience and fairness.

6. Venue is proper in this district under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. § 1391(b), (c) and (d) and because at all times relevant to the bringing of this action, Defendants transacted business, did business, were found or resided in the District of Columbia or because the claims alleged arose, in part, in this judicial district. In addition, as to Defendant Profarmaco, venue is proper pursuant to 15 U.S.C. § 1391(d).

III.

THE PARTIES

7. The States bring this action by and through their Attorneys General, individually and as authorized by law in a statutory, equitable and/or common law capacity, as representatives of, and as *parens patriae* on behalf of, natural persons; in their sovereign capacities on behalf of their respective states' general economies; and in their proprietary capacities on behalf of departments, bureaus and agencies of state government, as injured purchasers (direct, indirect, or as assignees) or as reimbursers under medical or pharmaceutical reimbursement programs.

8. Defendant Mylan Laboratories, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of Pennsylvania. Mylan's office and principal place of

business is located at 130 Seventh Street, 1030 Century Building, Pittsburgh, Pennsylvania 15222.

Mylan is engaged in the business of developing, licensing, manufacturing, marketing, and distributing generic and proprietary pharmaceutical and wound care products, including at least 91 generic drugs. In the twelve months ending March 31, 1998, Mylan had revenues of \$555.4 million and net income of \$100.7 million. Mylan Pharmaceuticals, Inc., a wholly owned subsidiary of Mylan Laboratories, is one of the world's largest generic drug companies. Mylan Pharmaceuticals is located at 781 Chestnut Ridge Road, P.O. Box 4310, Morgantown, West Virginia 26504-4310. Mylan Laboratories has ultimate control over the activities of Mylan Pharmaceuticals. Upon information and belief, UDL Laboratories, Inc., a wholly owned subsidiary of Mylan Laboratories, specializes in packaging technology and produces unit dose multi-source pharmaceuticals. UDL Laboratories is located in Loves Park, Illinois, and its mailing address is P.O. Box 2629, Loves Park, Illinois 61132-2629. Upon information and belief, at all relevant times, Mylan Laboratories has had ultimate control over the activities of UDL Laboratories.

9. Defendant Cambrex is a corporation organized, existing, and doing business under and by virtue of the laws of Delaware. Cambrex's office and principal place of business are located at One Meadowlands Plaza, East Rutherford, New Jersey 07073. Cambrex is engaged in the business of manufacturing and selling chemicals for pharmaceuticals, cosmetics, agriculture, and other industrial uses. In 1997, Cambrex had revenues of \$380 million and net income of \$17.8 million. Cbm Technologies, Inc. (Cbm) is a subsidiary of Cambrex located at 1 East First Street, Reno, Nevada 89501. Upon information and belief, Cbm was the primary contracting party, on behalf of Cambrex, in the exclusive licensing arrangements with Mylan described below. Upon

information and belief, at all relevant times, Cambrex has had ultimate control over the activities of Cbm.

10. Defendant Profarmaco S.r.l., a wholly owned subsidiary of Cambrex, is based in Milan, Italy and is located at Via Cucchiari, 7, I-20155, Milano, Italy. Profarmaco is engaged in the business of manufacturing chemicals, including APIs, and selling them to drug manufacturers in the United States and elsewhere. The API, which is the chemical that allows the drug to affect the body, is the most essential raw material for a pharmaceutical product. Upon information and belief, at all relevant times, Cambrex has had ultimate control over the activities of Profarmaco.

11. Defendant Gyma is a corporation organized, existing, and doing business under and by virtue of the laws of New York. Gyma's office and principal place of business is located at 135 Cantiague Rock Road, Westbury, New York 11590. Gyma is engaged in the business of selling APIs and other chemicals to the pharmaceutical industry. In 1997, Gyma had sales of approximately \$91 million. Gyma buys APIs from Profarmaco and other firms and resells them to generic drug manufacturers in the United States.

12. Defendant SST is a corporation organized, existing, and doing business under and by virtue of the laws of New Jersey. SST's office and principal place of business is located at 635 Brighton Road, Clifton, New Jersey 07015. SST is engaged in the business of selling APIs and other chemicals to the pharmaceutical industry. SST buys APIs from Fabbrica Italiana Sintetici SpA (FIS) and other firms and resells them to generic drug manufacturers in the United States.

IV.

CO-CONSPIRATORS

13. Upon information and belief, other persons, firms, corporations and entities not named as Defendants herein have participated as co-conspirators with the Defendants in the violations alleged in this Complaint, and have performed acts and made statements in furtherance thereof.

V.

THE GENERIC DRUG INDUSTRY

14. Generic drugs, which are chemically identical versions of branded drugs, cannot be marketed until after the patent on the branded drug has expired. Firms that manufacture and market generic drugs often specialize in such drugs, although Mylan manufactures both generic and branded drugs. Generic drugs typically are sold at substantial discounts from the price of branded drugs.

15. Mylan and other generic drug manufacturers require the approval of the United States Food and Drug Administration (FDA) to market a generic product in the United States. For each generic drug, the manufacturer must file an Abbreviated New Drug Application (ANDA) with the FDA to establish that its version of the drug is therapeutically equivalent to the branded drug. FDA approval of an ANDA takes an average of about 18 months, although the approval process can take two years or more.

16. Typically, the generic manufacturer purchases the API (Active Pharmaceutical Ingredient) from a specialty chemical manufacturer (API supplier). The generic manufacturer

combines the API with inactive fillers, binders, colorings, and other chemicals to produce a finished product.

17. To sell an API in the United States, the API supplier must file a Drug Master File (DMF) with the FDA. The DMF explains the processes that the API supplier uses to make the API and to test chemical equivalence and bioequivalence to the brand product. To use an API, the generic manufacturer's ANDA must refer to the API supplier's DMF filed with the FDA. More than one drug manufacturer can reference the DMF of the same API supplier. A generic manufacturer that wants or needs to change its API supplier must obtain FDA approval of an ANDA supplement, which includes a reference to the new supplier's DMF and test results regarding the generic manufacturer's product using the new API. This process can take as long as three years, with an average of about eighteen months.

18. Lorazepam and clorazepate are two of the approximately 91 generic drugs that Mylan currently manufactures and sells in tablet form. Lorazepam is used to treat anxiety, tension, agitation, and insomnia, and as a preoperative sedative. Doctors issue over 18 million prescriptions a year for lorazepam tablets. Because lorazepam is used to treat chronic conditions and is heavily prescribed for nursing home and hospice patients, lorazepam users tend to stay on the drug for long periods of time. Clorazepate is used to treat anxiety as well as hypertension, and in adjunct therapy for nicotine and opiate withdrawal. Doctors issue over three million prescriptions a year for clorazepate tablets.

19. Profarmaco and FIS both manufacture APIs in Italy. Both companies hold DMFs for lorazepam API and clorazepate API, and have supplied such APIs to drug manufacturers in the

United States. Foreign firms, like Profarmaco and FIS, that supply APIs to the United States typically have distributors in the United States who purchase APIs and resell them to generic drug manufacturers in the United States. Mylan purchases its lorazepam and clorazepate API from Gyma, Profarmaco's United States distributor of these products. Several other generic drug manufacturers have purchased lorazepam API from SST, FIS's United States distributor of this product. Mylan has never purchased FIS's lorazepam API from SST because FIS is not an approved lorazepam supplier for Mylan, -- *i.e.*, Mylan's ANDA does not reference FIS's DMF.

VI.

TRADE AND COMMERCE

20. At all times relevant to this Complaint, Defendants Mylan, Cambrex, Profarmaco, Gyma and SST participated in the market for generic pharmaceuticals throughout the United States.

21. Defendant Mylan manufactured, marketed, sold and distributed generic pharmaceutical products throughout the United States. Mylan's products were transported across state lines and were sold in the various states. The products sold and distributed by Defendant Mylan were shipped in interstate commerce.

22. Defendant Gyma is engaged in the business of selling APIs and other chemicals to the pharmaceutical industry. Gyma buys APIs from Profarmaco and other firms and resells them to generic drug manufacturers in the United States.

23. Defendant SST is engaged in the business of selling APIs and other chemicals to the pharmaceutical industry. SST buys APIs from FIS and other firms and resells them to generic drug manufacturers in the United States.

24. Defendant Profarmaco is engaged in the business of manufacturing chemicals, including APIs, and selling them to drug manufacturers in the United States and elsewhere.

25. Defendant Cambrex is engaged in the business of manufacturing and selling chemicals for pharmaceuticals, cosmetics, agriculture, and other industrial uses.

26. The activities of the Defendants, including manufacturing, marketing, distributing and selling pharmaceutical products, were in the regular, continuous and substantial flow of interstate commerce and have had and continue to have a substantial effect upon interstate commerce.

VII.

CONSUMER REPRESENTATION

27. The Plaintiff States, through their Attorneys General, bring this action, individually and as authorized by law in a statutory, equitable and/or common law capacity, as *parens patriae* on behalf of all natural persons residing in the Plaintiff States and, in those Plaintiff States where such class actions may be brought, pursuant to Rules 23 (a) and 23 (b) of the Federal Rules of Civil Procedure, on behalf of all natural persons residing in the Plaintiff States not otherwise represented by the Plaintiff States as *parens patriae*, who purchased lorazepam and/or clorazepate from January 1, 1998 to December 31, 1999.

28. There are thousands of consumers who purchased lorazepam and clorazepate from pharmacies and drug stores across the country at supra-competitive levels due to the conduct of Defendants.

29. Joinder of all consumer purchasers of lorazepam and clorazepate would be impracticable.

30. There are questions of law and fact common to natural person consumers of lorazepam and clorazepate, including:

a. whether the long-term exclusive purchase and sale agreements between Defendants for key ingredients needed to manufacture lorazepam and clorazepate create an unlawful exclusive agreement which unreasonably restrains trade under Section 1 of the Sherman Act, 15 U.S.C. §1;

b. whether the long-term exclusive purchase and sale agreements between Defendants for key ingredients needed to manufacture lorazepam and clorazepate create monopoly power under Section 2 of the Sherman Act, 15 U.S.C. §2;

c. whether Mylan unlawfully entered into the long-term exclusive agreement with Profarmaco, Cambrex and Gyma for the purpose of cornering the market of key ingredients used to manufacture generic finished pharmaceuticals;

d. whether Defendants Mylan, Cambrex, Profarmaco, Gyma and SST conspired to fix, raise or stabilize the price of lorazepam API under Section 1 of the Sherman Act, 15 U.S.C. §1;

e. the period and extent of Defendants' illegal conspiracy alleged herein;

f. the suitable measure of damages suffered by natural person consumers residing in the Plaintiff States resulting from Defendants' illegal conduct.

31. The prosecution of separate actions by individual consumers would create a risk of inconsistent or varying adjudications, potentially establishing incompatible standards of conduct for the Defendants.

32. Common questions of law and fact predominate over any questions affecting only individual consumers, including legal and factual issues relating to liability and damages.

33. *Parens patriae* and class representation by the State Attorneys General is superior to other available methods for the appropriate and efficient adjudication of this controversy, the State Attorneys General are the best qualified representatives and will fairly and adequately protect the interests of consumers, whether pursuant to *parens patriae* or class representation, and this action will eliminate the possibility of repetitious litigation, while also providing a remedy for claims too small to make practicable the expense of individual, complex litigation.

VIII.

RELEVANT MARKETS

34. There are four relevant markets: (1) the market for generic lorazepam tablets approved for sale in the United States; (2) the market for generic clorazepate tablets approved for sale in the United States; (3) the market for lorazepam API approved for sale in the United States; and (4) the market for clorazepate API approved for sale in the United States.

IX.

ANTICOMPETITIVE CONDUCT

35. In 1997, Mylan embarked on a strategy to raise the prices of some of its generic drugs and maintain these prices at inflated levels, thereby increasing the profitability of these drugs. One part of this strategy was to seek from its API suppliers long-term exclusive licenses for the DMFs of certain APIs selected by Mylan because of limited competition. If Mylan obtained such an

exclusive license, no other generic drug manufacturer could use that supplier's API to make the drug in the United States.

36. Ultimately, Mylan sought exclusive licenses for the DMFs for lorazepam API and clorazepate API.

37. Mylan began negotiating for exclusive licenses with Profarmaco and its distributor Gyma, which sold lorazepam and clorazepate APIs to Mylan. The parties negotiated at meetings in Bologna, Italy; in London, England; and in New York. These negotiations concerned Mylan's proposal to Profarmaco that Profarmaco license exclusively to Mylan, for ten years, Profarmaco's DMFs for lorazepam and clorazepate API. The exclusive licenses would provide Mylan complete control over Profarmaco's entire supply of lorazepam and clorazepate API entering the United States market.

38. Prior to these negotiations, Gyma sold Profarmaco's lorazepam API to Mylan, Watson Pharmaceuticals, Inc. (Watson), and Purepac, a subsidiary of Faulding, Inc. (Purepac), and its clorazepate API to Mylan and Watson. Purepac and Watson are generic drug producers that compete with Mylan. At this time, Profarmaco (through Gyma) was the only source selling lorazepam and clorazepate API to generic manufacturers in the United States. FIS, which previously had supplied the United States market with lorazepam API, recently had exited the market because it no longer had any customers. With complete control of Profarmaco's supply of these products, and by refusing to sell any to its competitors, Mylan could deny its competitors access to the most important ingredient in manufacturing lorazepam and clorazepate tablets.

39. In return for the ten-year exclusive licenses, Mylan offered to pay Cambrex, Profarmaco, and Gyma a percent of its gross profits on its sales of lorazepam and clorazepate tablets, regardless of whether Mylan purchased the API from Profarmaco through Gyma. The profit sharing percentage offered by Mylan was smaller for lorazepam than clorazepate. As Mylan explained to Cambrex, Profarmaco, and Gyma, the reason for this difference was that Mylan intended to seek a similar exclusive agreement on lorazepam API with FIS, a competitor of Profarmaco, and with FIS's distributor, SST. Under this proposed agreement, Mylan would also pay FIS and SST a certain percent of Mylan's gross profits on lorazepam tablets, even though Mylan could not utilize FIS lorazepam API due to FDA regulations.

40. In October 1997, Mylan approached SST, FIS's distributor of lorazepam API in the United States, regarding a possible second exclusive licensing agreement for lorazepam API. The intent of this approach was to deny Mylan's competitors an alternate source of lorazepam API. Because of FDA regulations which require a manufacturer's ANDA to reference the DMF of its supplier, Mylan could not even use FIS's lorazepam API. Before Mylan could use FIS's product, it was required to supplement its ANDA, which could take an average of 18 months. Mylan explained to SST that it intended to raise the price of lorazepam tablets by controlling the supply of lorazepam API. In exchange for this exclusive license which would prevent any Mylan competitor from using FIS's lorazepam API, Mylan offered SST a percent of Mylan's gross profits on lorazepam tablets. Under this proposal, SST would receive these profits even though Mylan would not purchase from SST any lorazepam API. SST turned down Mylan's proposed licensing arrangement.

Had SST accepted, none of Mylan's competitors would have been able to use FIS lorazepam API to make or sell lorazepam tablets in the United States.

41. Sometime in the fall of 1997, Mylan approached Abbott Laboratories, the manufacturer of Tranxene, the brand name clorazepate product, which manufactured clorazepate API for its own use and thus was a possible supplier of clorazepate API for the generic clorazepate tablets market. Mylan inquired about purchasing clorazepate API, even though before Mylan could use Abbott's product, it was required to supplement its ANDA, which would take an average of 18 months.

42. Profarmaco signed the ten-year exclusive agreements licensing the two DMFs to Mylan on November 14, 1997. Through these agreements, Mylan obtained control over the supply of Profarmaco's APIs for lorazepam and clorazepate in the United States, denying Mylan's competitors (particularly Gyma's customers Watson and Purepac) access to these essential raw materials. In 1997, Profarmaco, through Gyma, supplied over 90% of the lorazepam API and 100% of the clorazepate API to generic manufacturers in the United States market. In separate agreements, Mylan agreed to pay Gyma a percentage of Mylan's gross profits on the sale of lorazepam and clorazepate tablets as compensation for Gyma's role in the negotiations leading to the exclusive licensing agreements with Profarmaco.

43. Without a source of supply, Watson and Purepac attempted to secure alternate API suppliers. Recognizing that Mylan now had control over lorazepam API from Profarmaco, Purepac even approached Mylan to obtain some lorazepam API on an emergency basis. Mylan refused to sell this product to Purepac.

44. Shortly after Mylan signed the ten-year exclusive licensing agreements with Profarmaco, SST's president met in Pittsburgh, Pennsylvania, with the Mylan vice president who has responsibility for purchasing APIs. At this meeting, which occurred on or around November 20, 1997, SST explained to Mylan that it would not license FIS's DMF for lorazepam API to Mylan, at least in part out of concern that such an agreement could violate the antitrust laws. Nevertheless, through the Pittsburgh meeting, or otherwise in the course of their exchanges of information before and after it, Mylan and SST conspired and reached an agreement to fix, raise or stabilize the prices of lorazepam API.

45. On January 12, 1998, despite no significant increase in its costs, Mylan raised its price of clorazepate tablets to State Medicaid programs, wholesalers, retail pharmacy chains, and other customers by amounts ranging from 1,900 percent to over 3,200 percent, depending on the bottle size and strength. For example, a 500 count bottle of 7.5 mg clorazepate tablets increased in price from \$11.36 to \$377.00. On March 3, 1998, despite no significant increase in its costs, Mylan raised its price of lorazepam tablets by amounts ranging from 1,900 percent to over 2,600 percent, depending on the bottle size and strength. For example, a 500-count bottle of 1 mg lorazepam tablets increased in price from \$7.30 to \$191.50. The ultimate retail price to consumers was even higher. Mylan's competitors matched these price increases for lorazepam and clorazepate tablets. After the above-mentioned price increases were effected, departments, bureaus, or agencies of the governments of some States (or such States' assignors) purchased lorazepam or clorazepate tablets at supra-competitive prices from Mylan or its subsidiaries, including UDL Laboratories, Inc.

46. Shortly after Mylan raised its price of lorazepam tablets, and despite no significant increase in its costs, SST carried out its part of the agreement by raising the price of FIS lorazepam API by approximately 1,900 percent. SST sold FIS's lorazepam API to Geneva -- one of Mylan's competitors. Geneva has set its price for lorazepam tablets at approximately Mylan's level.

47. As a result of these substantial and unprecedented agreements and price increases for lorazepam and clorazepate tablets, many purchasers, including pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies, patients, consumers and others, have paid substantially higher prices. Moreover, some patients may have stopped taking lorazepam and clorazepate tablets altogether, or been forced to reduce the quantity they take, because they cannot afford them.

48. As a result of these substantial and unprecedented price increases on lorazepam and clorazepate tablets, Mylan, Cambrex, Profarmaco, Gyma and SST have profited, and continue to profit, from their unlawful conduct, to the detriment of consumers.

X.

LACK OF PROCOMPETITIVE JUSTIFICATION

49. The exclusive licensing agreements, and Defendants' other conduct intended to lock-up the supply of lorazepam and clorazepate API, lack any legitimate business or procompetitive justification. Moreover, any justification that may exist does not outweigh the substantial anticompetitive effects of Defendants' conduct.

50. The exclusive licensing agreements were not reasonably necessary to protect Mylan's supply of lorazepam and clorazepate API. Profarmaco never indicated that it was considering no